

National Kidney Disease Education Program Strategic Development and Planning Meeting

Meeting Summary

June 28 & 29, 2001

DAY ONE

Welcome (Dr. Thomas Hostetter, Director of NKDEP, NIDDK)

Dr. Hostetter welcomed all participants, and promised that this meeting would set the course of the National Kidney Disease Education Program (NKDEP). He thanked participants for their expected efforts and contributions, reviewed the meeting agenda, and noted that Dr. Josephine Briggs has been instrumental in starting this education program.

Introduction (Dr. Josephine Briggs, Director, Division of Kidney, Urologic, and Hematologic Diseases, NIDDK)

Dr. Briggs noted that the goal of this meeting is to lead the development of a national strategy for prevention of kidney disease and reduction of associated morbidity and mortality. At the National Institutes of Health (NIH), the goal is to develop a research agenda that investigates what is not yet possible; the NKDEP will seek to implement what is known to be possible, which is more difficult.

Several reasons for starting the NKDEP program include:

- a steady increase in new cases of kidney failure;
- high rates of cardiovascular disease (CVD) in people with kidney disease;
- high rates of “late diagnosis” — many people begin dialysis only after being seen in the emergency room;
- poor implementation of available strategies that can slow the progress of chronic kidney disease (CKD) and that could better and sooner prepare patients for dialysis or transplantation; and
- striking racial disparities in the number of new cases and in provision of optimum care. (For example, the risk of developing CKD in young African-American men is 20-fold greater than in the general population.)

Optimism is warranted, in part because of the unified voices urging the start of this program. Initiation of the NKDEP is the result of calls to action from:

- the renal community, specifically, the Council of American Kidney Societies;
- the Centers for Medicare and Medicaid Services (CMS; formerly the Health Care Financing Administration [HCFA]), which, with its access to ways to modify and influence care, has offered advice about prevention activities;
- primary care provider (PCP) (Dr. Briggs noted that Dr. Hostetter’s efforts have been significant in this arena);

- health care providers;
- industry partners; and
- others such as the National High Blood Pressure Education Program and the National Diabetes Education Program (NDEP).

A task force made five recommendations in the summer of 2000 for NKDEP's charge:

- Develop an integrated patient-centered message; do not focus only on the kidneys but on the risk factors that combine to create CKD.
- Emphasize outreach to high-risk minority groups.
- Develop new guidelines only if needed; use guidelines available from the Joint National Commission on High Blood Pressure, the renal community, and renal physicians.
- Translate guidelines into performance measures that can be used by health care providers to assess the effect of education programs.
- From the beginning, implement strategies for evaluation.

Dr. Briggs added a sixth recommendation to the charge: that the NKDEP continue to define new aspects of the NIH research agenda. Although the NKDEP will consider many strategies and how to address the needs of many patients, the program will ultimately be implemented one patient at a time. Dr. Briggs urged meeting participants to help the NIDDK define the necessary new mindset, the science, and the implementation of the possible.

Plenary Session

The Problem of Progressive Kidney Disease (Dr. Hostetter, NIDDK)

Dr. Hostetter distilled his overall view of the kidney disease problem in the United States as:

- A big problem exists.
- Imperfect though effective solutions to the problem are available.
- These known solutions are not being applied.

The scope of the problem. The United States has seen an enormous increase in patients with end-stage renal disease (ESRD). In 2000, almost 100,000 people entered ESRD, 300,000 were on dialysis and 70,000 had functioning transplants. These numbers have doubled since 1990 and are expected to nearly double again by 2010.

Cancer deaths in the United States in 2000 were 157,000 for lung, 57,000 for colon, 42,000 for breast, and 32,000 for prostate – compared with almost 100,000 people entering ESRD. Cancer rates are stable or declining, but the ESRD rate is increasing; the public has no idea about this prevalence or about the numerical preponderance of ESRD compared to death from most cancers.

Dr. Hostetter provided a synopsis of the prevalence of renal insufficiency in the United States, stating that as many as 10.9 million individuals have a serum creatinine level greater than 1.5 mg/dl.

Little is known about what happens to people with early kidney disease. Far too many of these people exist for currently available nephrologists to treat; twice as many nephrologists would be needed to see these people even once or twice a year. Primary care physicians must be integrally involved in managing CKD early on. Indeed, at present nephrologists generally see patients only at the late stages of kidney disease.

Although it is unknown whether renal insufficiency is a cause or a marker of CVD, people with chronic kidney disease run a significantly higher risk of CVD. The relative risk of CVD increases 1.4 to 2.05 times with a creatinine level greater than 1.5 mg/dl and increases 1.5 to 3.5 times with microalbuminuria; for people with ESRD, annual mortality from CVD increases 10- to 100-fold.

Costs of ESRD are high, at almost \$18 billion in 1999, representing 6 percent of CMS payments as well as \$2 billion to \$4 billion of lost income for patients. (For comparison, Dr. Hostetter indicated that the total NIH budget was \$15.6 billion for that same time period.) Although most minority groups have relatively higher risks of developing ESRD compared to Caucasians (for example, African Americans are 4.45 times more likely to develop ESRD), it is primarily Caucasians who use dialysis. Incident rates by age indicate that 64 or 65 is the average age of onset. Incidences of ESRD had been centered in “the Stroke Belt” (the Southeastern portion of the United States), but recent changes show an increase in ESRD in other areas of the country.

What can be done about this problem? Prevention of CKD is possible. Type 2 diabetes itself is maybe preventable through lifestyle changes, and renal complications of both types of diabetes are preventable. Hypertensive CKD is likely preventable; a blood pressure reading of 140/90 before renal injury occurs is posited to translate to no one needing dialysis for this disease.

CKD can be treated effectively. The African-American Study of Kidney Disease (AASK) concluded that the greater efficacy of angiotensin-converting enzyme (ACE) inhibitors lessens proteinuria and progression to ESRD. Many other studies have previously shown this effect in other diseases and populations. Low protein diets have been shown consistently to lessen progression as well.

How well are strategies being implemented? Strategies to delay progression to ESRD are infrequently employed. A study four years ago concluded that large numbers of hospital and medical center patients who had dipstick-positive proteinuria were discharged without being given ACE inhibitors.

Some solutions. Dr. Hostetter suggested the following possible solutions to the problem of escalating CKD and ESRD in the United States:

- Heighten awareness and education for high-risk groups and primary care providers.
- Find better disease and risk markers.
- Deepen the understanding of the epidemiology of renal insufficiency.
- Devise better therapies.
- Encourage system-level improvements, such as electronic prompts, routine reporting of calculated glomerular filtration rates (GFRs), performance measured for quality improvement (QI), and innovative strategies for care delivery.

Only a small number of patients in the United States are part of health care provider networks that would offer the above systematization, so it is imperative to heighten awareness and increase education for high-risk groups and primary care providers directly.

Kidney Disease from a Patient's Perspective (Ms. Linda Holomah)

Ms. Holomah presented an emotionally moving account of her perspective as a hemodialysis/ESRD patient seeking treatment. She has been receiving hemodialysis for more than 20 years, which she described as “the most formidable challenge of [her] life.” She currently receives dialysis at the Fort Washington (MD) dialysis unit. She painted a verbal picture of the dark and light sides of what it is like to be an ESRD patient.

(Note: The following write-up is presented as a transcript rather than in summary form, in order to preserve the essence of Ms. Holomah's important and moving message.)

There is a special place, a very special place, in which some people reside. This place of residence is in a dark wood, a place of immense trees, a forest of foreboding, massive obstructions, undergrowth, overgrowth. It's a dark place, an alone place, a confusing place where one has been sent to live. How is life supported in darkness? How does one arrive at this strange place? Is it an accident? A grand mistake? Is there a road out? Where is that road? It is not an accidental place; it's no mistake that one has been placed there. It is a place of intense operation. The fullness of the noonday sun is too bright for the delicate operations performed here. The only light that reaches this place jettisons through the dark wood as a laser in the night; it is lit by the subdued light of the moon. One must redirect one's eyes from the loneliness, the inward despair, and the desperate isolation of the dark to realize that there is indeed light and that one is not alone.

There is purpose in this place of deep question. It is the operation of the fashioning of gold by the moonlight. Gold by moonlight? Gold? Gold is precious – what can be found as precious hidden in this mass of darkness, desolation, and aloneness? Is gold not fashioned in a fire? Indeed there is fire in this dark crucible. The fire is not accidental, if one embraces the tender terribleness of this crucible. Choose the crucible? Accept this arena of fire? How so? But one must accept, for in acceptance lies peace. Many are found there; few accept where they are placed; even fewer learn the ways of the fire of the crucible. The crucible is the place where big and hard questions find answers, where that which is secondary is burned away, where that which is incidental is removed, where only that which is essential remains. Where, if one asks the questions that pertain to life, will one find the answer?

And so, one embraces this crucible, abandons to the fire, remains there to hear another message. The message one hears is a message of life, not death; a message of hope, not despair. It is a tune set to another key loftier than one could compose alone. It needed the fire of the crucible, the subdued light of the moon, and the tender terrible hand to write a message of life on the sentence of death. It is a place where, in the dark, one sees great light, for even in the darkness will there be light and life. Such can begin to describe my life as an end-stage renal patient receiving hemodialysis for more than 24 years.

I have been asked to share my life and to address, if possible, any strategies that may reduce the occurrence of renal disease in our community. I found it a greater challenge in my life to be able to embrace the reality of my essentially unchangeable condition than to retard its occurrence. This purely myopic and self-focusing view was not essentially nor intentionally selfish or self-absorbed in nature; it was a question of life or death. I found myself in deep water and no one taught me to swim.

The intrusive nature of the disease and its concomitant issues presented to me the most formidable challenge of my life. This challenge offered to me little opportunity to look outside of myself; indeed, its volcanic eruption essentially ripped the floor, ceiling, and sides away from my heretofore protected life. A routine physical examination for a public school teaching position resulted in abnormal levels of protein in my urine. My immediate referral to a urologist resulted in a full examination, a referral to a nephrologist, and a kidney biopsy. The results did not resolve the reason for the renal disease. Two years later, a Masters Degree in Reading and a second biopsy brought me to the imminence of hemodialysis. On March 1977, I received my first peritoneal dialysis treatment, then on an outpatient basis in the intensive care unit for 72 hours, every 4 days for over a month. After the insertion and healing of a bovine graft, I received my first treatment in an outpatient hemodialysis unit. I was 26. These days were early days, when most things were very new.

My family feared that I would die, and secretly I knew that the sentence of death had indeed been written for me. My husband went to work and he looked away from me, he couldn't look at me. He could not care for me; this was too strange a place for him also. He did not have many questions. He quietly closed the door to our bedroom as I returned home to rest from my treatment every other day, and his only question to me was when was I going to return to work. His dreams of prosperity were at stake; his world, through me, was torn asunder.

My father could not visit me. Silent, with his head dropped, he felt so helpless, afraid, and a failure. I was born prematurely and stayed in the hospital for a very long time. He always and secretly felt that I was special for something, but for what he never knew; certainly, not this.

My mother came. This mother love, tender love, that had never traveled alone anywhere, never driven a car, never ridden a bus – found her way to me 700 miles away in the intensive care unit of Brady Memorial Hospital in Atlanta, Georgia. She heard and didn't hear what the doctors said. She had some questions but could not ask. It was all so new to her; she merely wanted to be with me to help me. She did what she was told to do: she cooked for me, she weighed my food, she bought salt-free mustard, mayonnaise, and bread. She put hot packs on my over-sized arm. I was in a cloud; I really did not know what was going on. I was simply being kept from dying.

Being a reading specialist, I read. I read everything that my nurse friends could give me. I read and I read – the anatomy of the kidney, the function of the kidney, potassium, phosphorous, beans, tomatoes, potatoes, what not to do, what to do. I read it all and then I put the books away; I had read enough. I didn't pick them up again. There was no

answer to the one question I had in my heart: why did this happen to me, what did I do to deserve this, and how can I live?

How does one live without the one thing required for life? It seemed that death would be better than this life, to waste the ultimate rejection to this awful condition was my desire. I could think of no better way to fight and annihilate this opponent than to take my life. Certainly that had been my plan, but I had a change of mind, a change in direction. Instead of fighting, rejecting, denying, I asked a different question. Have you ever tried to rescue a drowning person who was still fighting the water? He cannot receive your hand of rescue. Have you ever tried to give an answer where there was no question being asked?

I found out that my body was sick, and that I could not change. And I, the part that ached inside with deep pain, was not my body. I also found that the “I” that was not my body was lost. Instead of wishing I was in a different place, wishing that this did not happen to me, wondering “why me?”, I wanted answers to the meaning of life. To wish that something had not happened was a fruitless denial of reality. It did happen. To try to wish it away burrows one into a silent, desperate depression of the worst sort. To need to know why it happened introduces one to an endless torture of shame, blame, and confusion that could not remove the reality of renal insufficiency. I began to ask different questions. The answer to a wrong question will definitely lead you in the wrong direction or nowhere at all; to have no question at all is to be dumb, lifeless, and estranged in an intimately invasive, life-changing opportunity.

So I embraced my reality. I joyed in the place that I was placed. I looked for meaning, not in the physical anomaly of it all but I looked for higher, deeper meaning and messages. I did not choose to be fed from that which was around me. Everything around me spoke of sickness, disease, need, and depravity. If I had breath, there must be life somewhere or indeed I choose not to breathe another breath. Such was the intensity of my personal search.

I knew the doctors were doing the best they could do; I did not blame them or wish they could do more. I knew the nurses were great servants of care; I had no anger toward them. I knew the machine was a gift of life; I embraced it as a part of my life as I would my right arm (certainly I could not despise my own flesh).

So my anger and confusion, desire to deny and reject, was transformed to acceptance. I relaxed from within and became a recipient of care, and care entered deeply into the hidden places of despair. I quieted from within and became refreshed from within. The refreshing from within spilled over and out. I was not my body, and I soon found that I had life from within in spite of the insufficiency of my physical body – the ravaging pains of weakness, blood pressure crashes, debilitating cramps, nausea, and all the associated distresses came to me. Yet they were insufficient to rename the inward place of rest that I was coming to find. I joyed in my place of living. I found an oasis in a dry place.

I found some significant answers in that place of rest amidst great storms of unrest. I conceived a child in the early years of my dialysis. After daily dialysis and 5_ months, I lost the baby due to an insufficient cervix. An accepted plateau of living became a mountain of jubilation that quickly exploded and disintegrated into a pile of what

appeared to be worthless debris. I went into shock. That which had been answers to my heart became no answer at all. I wandered for two years in utter detachment from a world that felt too cruel for the tender heart that had been mortally wounded. I was angry and felt that the God I knew could not be trusted. I put Him at arm's length, just far enough away that I would not have to ask any more questions, but I had to know more and I had to see more.

Since I still had breath, there was something to be known. I had not taken my life and I did not die; therefore, there must be more. I thirsted for deeper meaning to that which seemed to be utterly useless and cruel. My doctors, nurses, and family did all they could do. They couldn't take "it" away, they could not change "it." Some things cannot be changed, avoided, or averted no matter how much we try. Yes we try (we must try) but those of us who walk an unavoidable life where no one has walked need merely to face it and let the resounding inutterable answers speak where no one has spoken. Such has been the story of my life.

My husband of 16 years ultimately decided that his life would be better without me, choosing to create another reality apart from that which we lived together. He found no question appropriate to the reality and chose another in which to live. I do not know whether he found any answers there either, but his departure did not minimize nor abort or thwart the wealth of knowing that which is to be gleaned from each and every turn in my life. Choosing again not to be defined by that which occurs but being defined by that which is within, I continued to walk, ask, and know.

And so the walking and the living from within has continued. One year has expanded to over 24 years. I have been the recipient of hands of care from one unit to the next, and it has been only in the very recent days that I have, with deliberation, reached outside my private fishtank and momentarily peered out of the bowl to loving hearts of care wanting to reach within. (That's you!) I never knew of the many organizations working diligently, through research, education, programs, and innovation, on behalf of kidney patients and their families. Is it that the road from you to me is so complex, long, and winding that it has taken 24 years for you to reach me? Or is it that it has taken 24 years of me to be strong enough to reach out to see you there?

I don't know the answer to those questions, but I do know that there is a key to the reduction of the devastation of renal failure in addressing the patients' response to the trauma of renal failure. I have concluded that, just as there is sunshine in a day, there is night as an equal part of that day. I have concluded that there will always be sickness in the world, and we will always do our best to treat and cure every sickness that may beset Man. And for the part that we cannot do – and there will be a great part that we will not be able to do – we have a single response: we must remove our confidence from ourselves, for some things are bigger than we are. Some things hold mysteries that are completely outside of our grasp to understand, solve, and do. In those arenas, we must reduce ourselves and accept our reality as too great for us to change, to fight, and deny, and seek something bigger, grander, exalted. It may take us on a marvelous journey – mine has definitely been one – that will defy the monster that sought to destroy us. For it will lift us to another plane of life and living, far above that which we feared, and we will begin to look at it from above and find it not touching us at all. We will find life itself, not to be

found in this thing that we thought we lacked, but found indeed through that which we lacked catapulting us into a fullness of life and living.

So in the face of all the programs, innovations, advancements that will come, let us not forget this dimension – the most intangible of them all and the most essential to address. In this dimension, I have gained the greatest potential to share, to give, to educate, to relate, to live, to receive, to know life, to receive help, to dismantle fear, to have joy, to have hope, to not feel like I was dead and dying. In the quest for life, I learned how to live and 1 year became 24 and that which was essentially death to me.

Thank you to the many hearts and hands that have reached into my life by that which you have devoted your professional lives to do: making my life better one year after the other. It is indeed my pleasure to meet you face-to-face today, and it is my hope that I can assist in all that we attempt to do.

The Primary Care Physician's Role (Dr. Cynda Johnson, University of Iowa College of Medicine)

Dr. Johnson examined three possible ways to view the primary care physician's role in CKD and ESRD – no role, “roll with it” (having the role defined by various groups already empanelled), or “rock ‘n’ roll” (becoming an active partner in dealing with kidney disease).

The “no role” path can be argued because there has been no clear message to primary care physicians (PCPs), and most health plans have open access to specialists. PCPs believe “we can't do it right no matter what” because they are accused of referring too early or too late or of ordering too many or too few tests. PCPs are not generally considered part of the preventive task force on kidney disease.

The “roll with it” approach suffers from the major problem of too much information, with many groups telling PCPs what to do and promoting different guidelines. Barriers to active involvement by PCPs in kidney disease management include a request for focus on many chronic diseases at once, lack of consensus on guidelines among groups, variable insurance coverage, inconsistent responses following consultations, and feeling overwhelmed by the increasing numbers of people with CKD.

K/DOQI advisory board. At the Kidney Disease Outcomes Quality Initiative (K/DOQI) advisory board meeting on December 4 and 5, 2000, a discussion group on outreach to medical professionals developed the following consensus: “CKD is not perceived by clinicians to be an important problem, nor are they aware of the clinical manifestations of CKD. There is a definite need for awareness. This should be considered in guideline development.” Four problems were noted specifically:

1. Chronic kidney disease is a public health problem worldwide.
2. Adverse outcomes of CKD can be prevented or delayed.
3. CKD is under-diagnosed and under-treated.

4. Reasons for public health concerns include lack of uniform agreement on methods for clinical assessment, description of stages in progression of CKD, and stratification of risk for progression of CKD and development of cardiovascular disease.

A targeted approach for PCPs is needed. Primary care doctors need to be able to recognize CKD, identify the risks and target the high-risk groups, appreciate risk stratification and its relationship with chronic disease, understand what measurements are necessary, and know when to evaluate patients for CKD complications and when to refer patients to specialists. Clinical factors for PCPs to understand include the importance of urinalysis to check for protein, the value of GFR and prediction equations, the significance of obtaining height measurement on all patients, and the fact that a 24-hour urine collection is not needed (it is difficult to get patients to comply with this collection and is no more useful than “spot” determinations of urinary protein to creatinine ratios).

Dr. Johnson suggested several methods for intensifying the change process. Imparting knowledge about CKD and ESRD is key, through medical schools, board reviews for all boards requiring recertification, and journals. Getting the public interested in knowing their “numbers” (for example, teaching patients about their GFR number), similar to the campaign about knowing cholesterol levels, will force PCPs to change their interactions with patients. Advocacy for reimbursement for tests and patient interaction relative to CKD and ESRD will also help speed up the change process. Heavy press coverage will be effective, as will articles in the medical literature. Pharmaceutical representatives are listened to and could be used to transmit information. Especially for the younger physicians, Web sites and electronic updates will also be helpful.

Dr. Johnson conducted a quick (nonvalidated) poll of her colleagues regarding what PCPs know and do. Anecdotal responses included:

- PCPs only screen patients with risk factors, and only annually.
- The best way to manage CKD is to manage contributory diseases.
- One effective way to reach PCPs is through continuing medical education (CME) and journals.
- Routine screening is performed with elderly patients.
- To get the attention of PCPs, kidney disease guidelines should be part of general guidelines, because treating it separately is too difficult for physicians to remember.
- One PCP suggested that, to get the attention of PCPs, nothing should be on paper; other communication methods should be used.
- Most family physicians are unaware of ESRD.

Questions and Discussion from the First Three Presenters

Questions from Ms. Holomah’s presentation included:

1. *What kind of education do patients on dialysis receive?* In the 24 years she has been receiving dialysis, Ms. Holomah noted that minimal amounts of educational materials were easily available. Health care personnel were preoccupied with making sure patients got on the dialysis machine and got home; no education component was available in any of the dialysis units she used. She noted a current dearth of education materials; even the televisions in her current dialysis unit, which could be used for education via videotape, cannot be kept on. Early on, patients may be more

devastated than curious; once they are not quite so devastated, they are interested in maintaining their health but not necessarily knowing so much. Although it is unknown how much information is getting to patients, it is also unknown how much information patients really want.

A representative from the National Kidney Foundation (NKF), (Wendy Brown), offered to provide written material, for patients and families, to Ms. Holomah's dialysis unit.

A representative from the American Association of Kidney Patients (AAKP) (Chris Robinson) averred that little information existed 15 years ago. Some programs now provide material to patients before they start dialysis. Outcomes improve drastically when decisions are not made in an emergency situation. Many avenues and opportunities exist for reaching patients; using the Internet is more effective for physicians than for most patients.

A representative from the Medical Education Institute (MEI) (Dori Shattell) stated that a number of educational materials are available. The MEI is pilot testing a Web-based "Kidney School," which is an interactive kidney disease education program.

2. *Could patients on dialysis help in finding others in earlier stages of the disease?* Ms. Holomah responded that patients could help, theoretically, but most patients cannot see past their disease.

The MEI has conducted research asking whether patients want more information about their kidney disease; results indicate that patients are interested in more information but there is an upfront barrier of fear. Patients are afraid to die or they are afraid life will not be worth living; once that barrier is traversed, they can be receptive to more hopeful messages from health care professionals.

3. *What is being done right for patients on dialysis and what needs improvement? Are health care professionals listening well enough and providing necessary and appropriate advice?* Ms. Holomah noted that, 24 years ago when she first started dialysis, the environment was empty of both compassion and information; she felt she was being managed to die. In the past 3 years she found, through extensive interviews, a nephrologist who was a human being excited about helping people. Nephrologists should surround themselves with information about life (not death) and should exude and state a feeling of hope and a desire for partnership with the patient to manage the disease together. Treatment centers are unable to concentrate on the patient because of too many administrative issues; although it is not now the case, their message should come across as "I want to reach you to help you reach me, and to help you reach others."
4. *Would dialysis patients be willing to extend their experience to encourage others such as family members to be screened for proteinuria?* Ms. Holomah responded that timing is significant and barriers must be removed. An openness must be encouraged to talk about things people may be unwilling to face. The environment for the dialysis patient is delicate and obstacles exist to bringing a patient to the point of being willing to extend their experiences. The patient must be at the point at which she can care for

others and feel outside of herself. Reaching young people at risk for CKD will be the most significant challenge.

Questions from Dr. Johnson's presentation included:

1. *What do you want to measure and who takes primary responsibility for this testing?*
Dr. Johnson responded that the plan for consultation is to have a primary care doctor consider a consultation at the first recognition of abnormality related to CKD. Once that determination is made, an initial consultation with a nephrologist is in order. All kidney doctors should use the same consultation, targeting various areas of disease such as status of bone, anemia complications, GFR, and nutrition (most of which need to be checked when a GFR is less than 60); these consultation guidelines should be standardized on the website of the National Kidney Foundation. For every consultation that results in follow-up testing recommendations, the PCP and the nephrologist should decide who will be responsible for each test. It is quite possible that the PCP can follow the patient appropriately, with occasional consultation with the nephrologist; in that case, repeated referral is not necessary.

John Flack (Wayne State University) offered a comment regarding standardized consultation and referral: He was not sure that nephrologists want to see all the potential patients, in part because these visits will not represent significant reimbursements and also because not enough nephrologists are available currently. However, a PCP working in conjunction with a nephrologist might be more feasible. Competent PCPs can do most of the care for early renal disease, especially in consultation with a nephrologist (without actual referral).

Welcome from the Director, NIDDK

Dr. Hostetter introduced Dr. Allen Spiegel, Director of NIDDK. Dr. Spiegel apologized for his absence at the opening of this meeting and commended Dr. Hostetter's and Dr. Briggs' leadership for this program. He reminded participants that the statistics are clear: CKD and ESRD are costing a great deal in human and financial terms. Partnerships will be the key to making a difference.

The Role of Nursing (Ms. Ann Compton, Virginia Commonwealth University)

Ms. Compton spoke about a successful pre-ESRD program that is improving care and delaying the need for dialysis. Scientific and anecdotal evidence exists to support the health care benefits to patients and the financial incentives to payers of such programs.

As a nephrology nurse practitioner, Ms. Compton knew that predialysis programs save money. In 1996, she sought support for creation of a pre-ESRD program. Many of her patients at the clinic at Virginia Commonwealth University/Medical College of Virginia (VCU/MCV) were indigent and lived in inner-city neighborhoods. With the commitment of physicians, a designated coordinator, a multidisciplinary team, and an instructional designer, the program was designed to include a performance-based patient guide, class discussion, and a pocket laboratory card for tracking pertinent laboratory values.

Called “The Kidney Connection,” the 8-week program is offered every Tuesday for one hour prior to the renal clinic. Usually attracting 35 to 40 patients, the class runs continuously for an hour. Patients may attend the classes in any order, they may attend the class whether or not they have a dialysis appointment, and they may attend the class as many times as desired; family and friends are also welcome. Class topics include kidney function, dialysis options, transplantation, financial and adjustment issues, nutrition and diet, medications, high blood pressure, and patient support. The goals of this class include improving patients’ psychosocial, physical, and rehabilitative outcomes; improving functional status and quality of life for patients; easing the transition from CKD to ESRD; decreasing the need for urgent starts of dialysis; delaying the need for dialysis; reducing hospitalizations; improving patient compliance; better control of blood pressure and anemia; and reducing health care costs. This program is successful because of physician support and a patient referral system that works well. Patients report positive experiences in these classes, and improved patient outcomes have occurred (including increased knowledge).

Printing of the first patient guides was funded by industry. In return for associating the company name with the class, one pharmaceutical company developed posters and funded gift certificates. Other materials were funded by a scholarship from the American Nephrology Nurse Association (ANNA) and a grant from the NKF.

Ms. Compton reviewed the problems encountered in implementing “The Kidney Connection” and she enumerated the solutions utilized, including:

- *Different programs needed for different environments (“one size does not fit all”).* Successful programs can mentor programs with similar needs. The basic curriculum can be made available to all dialysis units, so that units can customize the program to their needs.
- *Time required to develop this program.* Time requirements are most intense in the planning and early initiation phases. Giving other units access to existing materials would reduce the time required to start up such a program and, eventually, the program would become a routine part of the work week. In the long run, time is saved by avoiding crisis/emergency intervention.
- *Timely referral of patients.* Marketing the program directly to patients and their families can help ensure timely self-referral, and collaborating with PCPs, nurse practitioners (NPs), endocrinologists, and diabetic nurse educators can help ensure timely referral by health professionals. Collaborations with other disease organizations and foundations – such as those centered on diabetes, hypertension (HTN), heart disease, and lupus – will encourage patient referral.
- *Lack of awareness of the effectiveness of early intervention.* Awareness efforts should concentrate on where programs are available and how they are useful. Marketing to patients will need to focus on making patients understand and believe that they are sick, and marketing to other health care professionals poses the challenge of educating them about the size and characteristics of the patient population.
- *Nursing shortage, even though enough dialysis machines are available.* Well-prepared, dedicated nephrology nurses or advanced practice nurses are pivotal to the success of this program, but a shortage of such professionals exists. Self-care shifts can be

organized that can safely increase the nurse-to-patient ratio, and home hemodialysis and other options (such as peritoneal dialysis) can be presented to patients.

Ms. Compton summarized her description of “The Kidney Connection” by noting that this program must be multidisciplinary in nature – a physician directs the care, a nurse coordinates and pays attention to the details of the care, a dietitian provides frequent dietary consultation, a social worker assists with financial and adjustment issues (patient compliance may depend on affordability), a pharmacist helps patients make sense of their medication regimens, and a transplant coordinator helps identify transplant candidates early. Patients and their families will benefit from this coordinated approach to care.

Problems and Opportunities for Payers (Dr. Stephen Jencks, CMS)

Dr. Jencks explained that the Centers for Medicare and Medicaid Services (CMS; formerly HCFA) is interested in how to improve quality care in the earlier phases of CKD/ESRD; half of renal failure cases occur under CMS coverage. As the average age of people with kidney failure goes up, more of those patients are on Medicare. CMS will continue to participate actively in the NKDEP because of its obvious stake in treating this disease early. Through Medicare, CMS is the world’s largest investor in quality protection and improvement, spending more than \$500 million a year (about 0.3 percent of the Medicare budget) on this monitoring and improvement function. Despite its size, CMS can only purchase quality care through partnership with other stakeholders and by actively working to create a consistent environment for quality improvement.

Currently, about 80 percent of hemodialysis patients are receiving adequate dialysis, and two-thirds of these patients are not anemic. The racial gap has been closing, such that between 1996 and 1999 minority populations are approaching the quality of care enjoyed by Caucasians.

Dr. Jencks noted that partnerships are critical. Unified purpose and messages increase impact and efficiency and lie at the heart of professional accountability; consistency among practitioners, plans, purchasers, certifying boards, and accreditors reduces the burden on everyone. Partnership opportunities can be divided into three areas – message (the need for improvement and the importance of systems), method (measuring performance and setting improvement priorities), and motivation (professionalism, burden reduction, and creating a business case for improvement).

Message. Dr. Jencks suggested the need to collectively envision a health care system that would be transformed from an art form that requires nearly superhuman individual performance to be safe, reliable, and effective to a system that would be inherently safe, reliable, and failure-resistant, to which professionals add skill, wisdom, judgment, and humanity. Total system reform is not likely, so focus should be centered on simple changes that need to happen. Those system changes should not depend on the physician, who obviously needs to inform the original changes but should not need to be doing so continuously. The reimbursement system must be changed such that, when money is saved, the money-saver should see the results of those efforts in some form.

Method. Partnerships for measurement are necessary for success. Dr. Jencks listed several possible partners, including the National Forum for Quality Measurement and Reporting and the Diabetes Quality Improvement Project. CMS is committed to measurement based on professionally developed guidelines. National topics in the Quality Improvement System for Managed Care (QISMC) and regional consortia around diabetes care could supply improvement topics for measurement. Specific methods for accomplishing improvement might include computerized order entry, assigning barcodes to patients, and providing standing orders for routine and recurrent services.

Motivation. Unity of message creates motivation and focus; one example is the American Medical Association's (AMA) Quality Alerts. National professional partnerships create opportunity for local partnerships; one example is the diabetes eye exam collaboration with ophthalmologists and optometrists. Purchaser partnerships focus on common quality goals, common information requests, and common measures, not necessarily on joint purchasing; one example is the Quality Interagency Coordination Task Force and business coalitions. Dr. Jencks stated that thoughtfulness and creativity, along with experiments and payment demonstrations, may strengthen the case to purchasers.

Partnerships. The epidemic of renal failure is hardly recognized, much less seen as something people need to work together on, so partnerships will be crucial. Dr. Jencks noted the following steps toward effective partnerships:

- Agree on the need for improvement.
- Focus on a systems approach and avoid blame.
- Make the business case for improvement ("improvement pays off").
- Use measures, but do not get stymied over small differences.
- Avoid letting opponents of partnership use turf issues to divide partners.

Lessons learned from prior CMS partnerships include:

- Every individual or group who shares any of the improvement goals is a potential partner.
- Partners need not endorse one another. Be cautious about the notion of not being able to move forward until everyone agrees; it is only necessary that everyone be seated at the table.
- Trust is not always available; it is a result of a partnership, not a prerequisite. Skittishness abounds about entering into partnerships.
- National and local levels of partnership work in parallel and support one another, but implementation is accomplished mostly at the local level by local partnerships.

CMS's approach to quality improvement. CMS is approaching QI through the use of partnerships, systems improvement, and multiple parallel strategies. Dr. Jencks reviewed the Health Care Quality Improvement Process in Value-Based Purchasing, a flow diagram that shows a range of available interventions that match purchasing strategies.

The Peer Review Organizations' (PROs) mission is to improve the effectiveness, efficiency, economy, and quality of services for which Medicare pays. It consists of a system of 53 contractors (1 per State), funded from the Medicare trust funds and administered by CMS. The budget for the PROs is about \$350 million per year. PROs are working on national priorities of a public health strategy and are using an education approach, a

strong emphasis on promoting systems improvements, objective statewide measurement of results, and wide latitude for intervention approaches.

Dr. Jencks summarized his presentation by noting the steps for organizing for success:

- Agree that the goal is important and achievable.
- Agree on performance measures to be improved and how to collect those measures.
- Build partnerships among stakeholders.
- Identify practical systems improvements that everyone can adopt.
- Create a business case for improvement.

Managed Care Plans (Dr. Roger London, Oxford Health Plans)

Dr. London emphasized that each managed care plan is unique by stating that, “If you’ve seen one payer, you’ve seen one payer.”

Research on resource utilization. Dr. London reviewed his research at Oxford Health Plans entitled “Resource Utilization Pattern of Patients During Pre-Dialysis.” The objective of this research was to evaluate the costs and utilization of health care services for patients during the year prior to initiating dialysis, with the goal of improving quality of care and reducing future costs. The data source for this research was the proprietary managed care (MC) database of 3 million lives from a variety of plans in 22 States; approximately 72 percent of the MC database individuals belonged to HMO or PPO plans. The research method used was a retrospective analysis of administrative, outpatient, pharmacy, facility, and medical claims from January 1, 1997, to December 31, 1999.

A profile of 1,936 patients was derived for this research; 46 percent were female and 54 percent were male, the mean age was 66.8 years, and nearly 90 percent received hemodialysis (with 2.5 percent receiving peritoneal dialysis and 7.6 percent receiving both forms of treatment). Clinical information about these patients showed an average of eight comorbidities per patient, with hypertension, diabetes, and congestive heart failure (CHF) the most common non-renal comorbidities. Anemia was evident in 52.2 percent of patients. Resource utilization and cost analysis showed that the mean charge per patient, including facility, professional, and pharmacy services, was \$37,330 (a figure that Dr. London predicted would “get HCFA’s attention”). Data on inpatient utilization for these patients indicated there were 1.3 admissions per patient per year, with an average length of stay of 7.8 days; CHF was the most frequent discharge diagnosis. Inpatient costs increased significantly in the 3 months immediately preceding dialysis.

Dr. London provided summary and conclusion information from his research as follows:

- Significant health care resource consumption occurs in the year before renal replacement therapy (RRT), in association with many comorbid conditions.
- Hospitalization occurs frequently and late in the pre-dialysis course, and it is the major driver of costs.
- The CKD population was incompletely identified by administrative data alone, and approximately 50 percent of CKD patients had not seen a nephrologist prior to dialysis.
- The population identified was seriously under-managed.

- With a focused effort, many of the hospital admissions could be prevented.
- Late placement or under-use of vascular access can be corrected.
- Inappropriately low use of erythropoietin, iron, phosphate binders, and vitamins, and high use of nonsteroidal anti-inflammatory drugs (NSAIDs) can be addressed.

Strategic opportunity for payers. Dr. London stated that the CKD population presents an excellent opportunity for quality improvement, primarily because guidelines for referral and late management exist and these patients are under-managed at present. In addition, interventions for comorbidity and dialysis initiation are well known, costs for CKD patients are nearly equal to that of the ESRD population, and interventions are likely to reduce costs in both the CKD and ESRD populations. Based on this obvious opportunity, Oxford Health Plans decided to plan and implement a disease management strategy that would link CKD patients to existing ESRD disease management programs, concentrate on CKD patients lacking referral to nephrologists, and leverage the existing ESRD, CHF, and diabetes disease management programs by getting more patients into these programs. With the goals of encouraging early intervention and education, facilitating referrals to nephrologists, and promoting non-emergent access placements and non-emergent initiation of dialysis, Oxford chose to focus its efforts on CKD patients who had not seen a nephrologist and who had diabetes and CHF comorbidities. Measurements chosen were clinical outcomes, financial data, patient satisfaction, and functional status.

Interventions were four-fold:

1. Referral involved a letter to the PCP with a followup call to the PCP to confirm referral, a letter to the nephrologist, and a member followup call to ensure the nephrologist referral and that an appointment was made and kept.
2. Guidelines used were the NIH and Health Plan Guidelines, which were disseminated to nephrologists and PCPs.
3. Patient education included mailing educational information and baseline clinical assessment questions.
4. Disease management included referral to diabetes and CHF programs.

Dr. London noted some of the challenges for nephrologists, PCPs, and payers. For nephrologists, the 2,500 practicing nephrologists in the United States cannot care for the 8 million expected CKD patients (this ratio would be more than 3,000 patients per physician), current reimbursement provides incentives for nephrologists to care for ESRD patients but not for CKD patients, and nephrologists are not trained to perform patient education. For PCPs, the average PCP has 80 CKD patients within their 2,500 to 2,800 patient population and reimbursement incentives for PCPs make it unlikely that they will devote time to education and cognitive management.

Payer considerations were summarized by Dr. London as:

- Guidelines for care interventions, when issued, will require coverage payment policies for patient education providers (nurses, dietitians, and social workers) to ensure implementation.
- These guidelines will also require coverage payment policies for the medications integral to the care interventions (for hypertension, diabetes, lipids, bone disease, and anemia).

- Plans will look for compliance measures within the guidelines that can be derived primarily from administrative data.

Lessons Learned from NIH Education Programs (Dr. Hostetter)

Dr. Hostetter asked participants to notify him if people or organizations are not represented at this meeting but should be involved in the process of forming the NKDEP. He noted that the diabetes associations had been meeting this week so they could not attend. He then introduced the next portion of the meeting as an important opportunity to learn about the existing education programs at the NIH, noting that both the high blood pressure and the diabetes programs will provide lessons learned that will be applicable to NKDEP.

National High Blood Pressure Education Program (Dr. Edward Rocella, NHLBI)

Dr. Rocella noted that it has been 30 years since the Health, Education, and Welfare Secretary was implored to implement a national high blood pressure (HBP) education program because of the irrefutable data about the benefits of lowering blood pressure (BP). Launched by Ted Cooper in 1972, the National High Blood Pressure Education Program (NHBPEP) is a cooperative effort among professional and voluntary health agencies, State health departments, and community groups. Administered and coordinated by the NHLBI, the NHBPEP's goal is to reduce death and disability related to high blood pressure through programs of professional, patient, and public education. Components of the NHBPEP include:

- mass media campaigns;
- community capacity building programs, working with State health departments to provide technical assistance to develop their own programs;
- population-based approaches to BP reduction, such as working with the food industry to lower salt in the food supply (because even small BP reductions of 2 mm translates to a 7 percent reduction in strokes in the population);
- advocacy building capacity, working with organizations to support them to become advocates;
- patient education programs, either by assisting in material development or by providing the material directly; and
- professional education programs.

The NHBPEP coordinating committee's major issue is consensus, since 45 different organizations are represented on the committee. The coordinating committee brought order to the chaos of hypertension issues; the disagreement that still exists within the committee is managed by asking for the evidence supporting dissenting opinions. Recommendations carry much more weight if all 45 organizations agree in public; the result becomes common practice.

For the NKDEP, the consensus issue will be critical – definitions themselves will matter little in the long term; what will matter most is that the program speaks with one voice and puts forth one set of guidelines. If a national kidney disease organization is to thrive, there must be a mechanism to speak with one voice and that voice must be supported. No program can exist if each constituency has its own definition or guidelines.

Dr. Rocella described the following five lessons learned from the NHBPEP that could be translatable to the NKDEP:

- **Achieve consensus and support the leadership.** Joint national committee reports should be released and it is crucial that all partnering organizations endorse the report. Consensus reports provide the public and the profession with one document that all organizations use and encourage their constituencies to adopt. Without such public consensus, the public and health care professionals will adopt the attitude of “The experts don’t agree, so why bother?”
- **Leverage resources.** Leveraging is important because no education budget is ever enough, and some necessary activities simply cannot be purchased. Dr. Rocella provided an example of an education program started by life insurers after they uncovered actuarial data that showed that people with lower blood pressure live longer (and thus insurers would pay out life insurance later). As an opportunity to develop an education program to reduce mortality, more than 75 percent of insurance companies were interested. No amount of money could have purchased that kind of interest and activity.
- **Constantly monitor the science that drives the program.** For example, data from the Framingham Heart Study showed relatively insignificant differences through year 5 in CHF incidence rates between people with normal BP and those with stage 2 hypertension. However, the data from year 10 and beyond did show a significant difference in CHF incidence rates. In addition, the fact that the U.S. population is getting older will highlight the importance of reviewing CHF prevalence data by age and taking a fresh look at antihypertensive treatment in older people. The NHBPEP has partnered with the Alliance for Aging Research to encourage clinicians to be more aggressive in treating hypertension in older people, especially to pay more attention to systolic blood pressure levels.
- **Develop measurable objectives.**
- **Look for program markers constantly and be willing to shift program focus when appropriate.** For example, reduction of stroke incidence in the Southeast “Stroke Belt” target has meant that States outside of that area now need more assistance and education focus, causing a shift in personnel and other resources.

Dr. Rocella summarized the NHBPEP’s most significant lessons as:

- “Just because people do not think like us does not mean their ideas will not be better than ours.”
- “In consensus, no one always gets their way.”
- “Science must drive the program and must be monitored constantly.”

National Diabetes Education Program (Dr. Charles Clark, Indiana University School of Medicine)

Dr. Clark described the National Diabetes Education Program (NDEP) as a Federally sponsored initiative, involving public and private partners, to improve the treatment and outcomes for people with diabetes, to promote early diagnosis of the disease, and, ultimately, to prevent its onset. Current scientific evidence demonstrates that much of the morbidity and mortality of diabetes can be eliminated by aggressive treatment with diet, exercise, and new pharmacology approaches to normalize blood glucose levels. However, a wide gap still exists between current and desired diabetes care and practices. In

addition, public awareness about diabetes is low, despite the fact that the disease is one of the leading causes of death and disability in the United States, affecting an estimated 16 million Americans, including 5.4 million who are undiagnosed. The goal of the program is to reduce the morbidity and mortality associated with diabetes and its complications.

NDEP's objectives are:

- To increase public awareness of the seriousness of diabetes, its risk factors, and potential strategies for preventing diabetes and its complications.
- To improve understanding about diabetes and its control and to promote better self-management behaviors among people with diabetes.
- To improve health care providers' understanding of diabetes and its control and to promote an integrated approach to care.
- To promote health care policies that improve the quality of and access to diabetes care.

The NIDDK and the Centers for Disease Control and Prevention (CDC) are jointly sponsoring the NDEP, along with several public and private organizations. The NDEP's target audiences include people with diabetes (primarily those with type 2 disease) and their families, the public, minority populations (African Americans, Asian Americans and Pacific Islanders, Hispanic Americans, and American Indians), health care providers, and health care payers, purchasers, and policymakers.

Five major components make up the NDEP: a partnership network, awareness campaigns, special population work groups, community interventions, and health systems. Dr. Clark explained that the purpose of the partnership network is to mobilize a critical mass of public- and private-sector organizations at the national, state, and community levels to partner and collaborate with the NDEP to change the way diabetes is treated. The focus is on dissemination, information sharing, and networking among the approximately 200 partner organizations that reach NDEP audiences.

In addition to the lessons already presented by the NHBPEP, Dr. Clark added one other lesson from the NDEP: the NKDEP should consult with the various target audiences and then develop its message(s), not the other way around.

Dr. Clark described the four major targeted special populations groups, all of which are the same target groups for the NKDEP:

- The African-American campaign utilized a family focus and an all-star (sports-related) campaign.
- The Hispanic/Latino campaign focused on understanding that something could be done to treat type 2 diabetes; members of the Latino community were generally quite fatalistic about the disease.
- American Indians harbored a fatalistic attitude about diabetes but also held a strong belief in preserving their culture, so this campaign used "future generations" reasoning.
- The Asian-American/Pacific Islander campaign was challenged by the 52 different languages within this population and by the high percentage of immigrants who lack resources and access to health care. The campaign focused on print media and on the top populations, concentrating on two main attributes — respect for authority and focus on the family.

Questions and Comments for Both Presenters

1. *Where should the NKDEP start?* Dr. Clark suggested that the NIDDK convene a relatively small group to define problems, messages and primary audiences. For the NDEP, the primary problem was that people (including physicians) did not take diabetes seriously and, therefore, patients were not being treated. The initial group then decided to focus on a single measure (blood sugar). Because patients were not demanding the kind of care they needed, the group decided to focus its education efforts on creating demand for care among the at-risk populations.

Dr. Rocella suggested the following first steps:

1. Collect the information that identifies the problem.
2. Identify the organizations that can do something about the problem (including nontraditional healthcare groups).
3. Identify the messages to disseminate – patient messages, public messages, and clinical messages – and get agreement on those messages.
4. Alert the public about the problem and encourage health care visits to discuss the problem; for example, encourage people to ask their doctors why their BP is high. Called “push-pull,” this strategy builds advocacy and also reaches out to professionals.

Dr. Rocella noted that this is a long-term process, but the NKDEP should be planned out so that progress will be detectable in years to come.

2. *Does either program have experience in reaching people who are not health-literate (one-fourth to one-third of the population)?* Dr. Rocella suggested identifying groups of people who can help; for example, the NHBPEP convinced the scriptwriters for the “White Shadow” television show to incorporate the problems of high blood pressure into Rosie Greer’s character. Poster contests among school children have been effective, as has working with church populations and sporting event promoters. Dr. Clark stated that NDEP produced a song that was played in the Latino community. African-American, Latino, and American Indian populations are aware they have a problem and devoured whatever materials were provided. He suggested consulting directly with the populations to find out whom they listen to, and then involve those influential people and institutions in developing the kidney health messages; for example, the NDEP worked with beauty shops because they were a place to congregate in the African-American community.

3. *How can NKDEP maintain the integrity of messages across each of the three NIDDK education programs? How can NKDEP get these same constituencies to buy into CKD issues?* Dr. Clark responded that it is crucial that the NKDEP not send out a different message; PCPs already have too many standards of care with which to deal. He also suggested that the program focus on where gaps exist and finding a niche for the NKDEP. Cross-incorporation of messages and standards among the three education programs will be critical. Dr. Rocella suggested keeping communication lines open among the three groups. All three education programs should speak with one voice, because one variation in the message will spoil all the messages; clinicians cannot handle multiple messages that should be unified.

4. *How should NKDEP approach the different subgroups within each minority group (e.g., income and education levels)?* Dr. Rocella answered that the NHBPEP would like to produce generic kits for organizations to develop messages to their own constituents. One kit is already available on the Web; the planning tools can be customized at the local level. Dr. Clark noted that, through the CDC, the NDEP has funded a number of organizations' materials; these materials are not copyrighted, so each organization can append its own logo and call it their own.

Breakout for General Strategic Planning

Participants broke into six small work groups to provide detailed input on the following aspects of the NKDEP program: goal and objectives, target audience(s), messages and strategies, partners, and evaluation. Breakout group questions were as follows:

1. **Program Goal and Objectives:** What are the primary issues that have not been discussed? Are some issues more important than others? What should the goals and objectives of the program be? How big or narrow should the program be? (How many target audiences? What level of program involvement – awareness campaigns, guideline development, health care policy changes through HCFA?)
2. **Target Audience:** What should the target audience(s) be? Who is most affected? Prioritize them. For each target audience, what is the biggest need in terms of the program? What barriers does each audience face? How can we best reach each audience?
3. **Program Messages and Strategies:** What are the key pieces of information that each identified target audience needs to know? What programs, materials, partnerships, and messages already exist? What kind of media attention has been placed on kidney disease? What are the gaps (prioritize the top three needs)? What do you see as the best role for NIDDK? For HCFA? For other Federal agencies? What major activities and approaches would be appropriate to fill these gaps?
4. **Program Partners:** Who else should be involved? What sectors? What specific groups? Why? In general, what are some of the things your group might do? What ideas do you have to work together in this program? What programs has your organization planned?
5. **Evaluation:** What evaluation measures should we use? Are there models of evaluation that would be helpful?

DAY TWO

Opening (Dr. Hostetter)

Dr. Hostetter introduced Mimi Lising, NKDEP Associate Director, who joined the program about 6 months ago. She has a Masters degree in Public Health and experience in health education, having worked in the diabetes education program. Ms. Lising was instrumental in organizing this meeting.

Breakout Session Reports from Day 1

Group 1 — Dr. Cynda Johnson, University of Iowa College of Medicine, and Dr. William Owen, Duke University Medical Center

Group 1 developed the following guidance outline for the NKDEP program.

Main Messages

Contextual background for the NKDEP:

- Use “broad strokes” before setting out the details.
- Develop several parallel components.
- Capitalize on existing systems or groups and use what they have already worked out.
- Align education and testing activities with current groups.

The NKDEP program goal is education.

NKDEP’s core message, which should aim to raise awareness through uniformity of message and targeting of all groups (patients, doctors, payers, and laboratories):

“CKD is a common health problem and its incidence is on the rise. Early recognition is beneficial because early stages can be detected by testing and treatment at early stages slows progression.”

Possible choices for target audiences:

- Patients diagnosed with diabetes or hypertension
- Patients with risk factors for CKD
- People with markers but without otherwise known disease
- The entire population

Suggested targeted audiences (limited to two from above list of four, due to resource limitations) and suggested approaches:

- Patients diagnosed with diabetes and hypertension: refer to existing groups (NDEP, NHBPEP, Kidney Konnection, etc.) and use clinical practice guidelines and clinical performance measures for testing.
- Patients with risk factors for CKD: refer to primary care providers.

“ABCs” for the primary care physician (tests that need to happen in the PCP’s office):

A is for albumin (using dipstick urinalysis)

B is for blood pressure

C is for creatinine (or some other marker of kidney function)

Other important points

Prediction equations will be critical; changing to prediction equations must be part of the initial plan. Urge pharmaceutical companies to help. Give doctors nomograms. Laboratories need to be pressured to make the change to prediction equations, but need to ensure they have all the pieces to create them. If the NIH mandates this change, it will occur.

This group supported the idea of enumerating stages of kidney function, similar to what has been worked on for K/DOQI – to drive thinking, to support the public message of knowing one’s number, and to drive the action plan. Creating a “stages of kidney function” measure (e.g., stages 1 to 5) allows patients to know where they fit.

Important principles for PCP consultations with nephrologists include clear messages about their desire for referrals, consistency in responses, positive feedback to the referring PCP, and treating this relationship as a partnership. The group suggested a Web-based consultation form.

Payers can understand the value of financing early detection, but only if there is a financial incentive (or at least not a disincentive). Payers can help support measurements to identify success, and their help is crucial in dealing with coding and reimbursement issues and implementation.

Consensus of the group was that, through coding and billing mechanisms, patients should be coded for renal insufficiency in addition to ESRD.

Education focus should be on early stages of CKD in a first packet of materials, then a later pre-renal replacement therapy package should be created. Modules or toolboxes could be created for different education packages. Information to patients should be the primary focus of NKDEP’s education activities, but physicians and other stakeholders need to know and understand their part in this educational enterprise.

Group 2 — Dr. Alan Kliger, Yale University School of Medicine, and Dr. John Flack, Wayne State University School of Medicine

Group 2 developed the following guidance outline for the NKDEP program.

Goals of the NKDEP:

- To establish CKD as a public health pandemic (not just an issue).
- The goals of Healthy People 2010 should be reviewed, as specific goals relevant to CKD may have been articulated already and could be reworked as education goals.
- Publicize risk factors for and predictors of ESRD, as well as comorbid conditions that take the lives of ESRD patients and for which earlier intervention can make a difference.

- Convince PCPs they can care for CKD patients. PCPs need to be empowered to manage patients with CKD, use a consistent message, and encourage partnership with the nephrology community.

Target audiences:

- Patients in high-risk groups – individuals with hypertension and/or diabetes.
- Relatives of CKD/ESRD patients. (A model already exists in Virginia.)
- High-risk demographic groups.
- Medical community at many levels. (There are many caregivers at many different levels of care.)

This breakout group attempted to prioritize target audiences and much discussion ensued about how to deal with limited resources. Group members hoped for adequate funding to be able to reach patients as well as the medical community, so that both could be targeted simultaneously.

Message:

- Keep the message simple; for example:
 - “Know your kidney number.” (Perhaps use GFR.)
 - “Ask your doctor.” Motivation is needed for patients to do this; marketing directly to patients and their families may motivate them.
 - “What you can do about CKD.” This component is necessary so patients do not feel helpless or hopeless.
- Keep messages consistent, to the public and to the medical community.
- Make the message evidence-based and, thus, able to be fine-tuned in response to current evidence.
- Use the building-block approach; the whole message does not have to be built at once and can be built in stages.
- Tailor the message to individual target audiences.
- Most important (as learned from the experience of other education programs): Focused risk groups should determine specific messages. First identify the groups and know the basic messages to be conveyed, then help the individual interest groups develop a message targeted specifically to their group.

Possible program partners:

- Industry (and industry funding)
- Employers and insurance companies
- Disease management organizations (DMOs)
- Culturally diverse patient advocacy groups
- Professional organizations, including pediatrics and geriatrics
- Non-health partners, such as the American Association of Retired Persons (AARP) and the National Caucus and Center on Black Aged (NCBA).
- High-profile stars can have significant impact on the general population.
- Other groups; for example, college fraternities and sororities

Evaluation to assess success should be set up in advance:

- Use quantitative and qualitative measures; find out from evaluation professionals who does the needed kinds of assessments.
- Review models available from the CME and the Advertising Council.

- Review other program evaluation tools, for example, from the NDEP.
- Establish early a work group to design program evaluation. Include education professionals.

**Group 3 — Dr. Wendy Brown, St. Louis University School of Medicine, and
Dr. Daniel Stryer, Agency for Healthcare Research and Quality**

Group 3 developed the following guidance outline for the NKDEP program. This group suggested a name change from NKDEP to NKHEP (National Kidney HEALTH Education Program), to reorient the focus to health rather than disease.

Program goals and objectives:

- Decrease incidence and prevalence of ESRD.
- Decrease the rate of growth of the ESRD population.
- Increase time from diagnosis to progression.
- Identify early the individuals at risk.
- Educate PCPs in a way that is easily “digestible.”
- Focus on early identification, not just talking about ESRD.
- Focus on identification of risk and prevention and intervention strategies.
- Start with the youngest groups.
- Include smoking issues in kidney education.

Target audiences, using a multilevel approach:

- CKD patients at different stages when first identified
- High-risk communities and populations
- Families of ESRD patients
- Primary care providers
- Health professional schools – early in the education of health professionals, it is important for them to be aware, through the curriculum, of the important issues and how to identify individuals at risk

High-risk communities and populations include:

- minorities
- patients with diabetes
- families of ESRD patients
- patients with hypertension
- obese patients
- patients with proteinuria
- children with congenital and hereditary disorders

Three priority program messages and strategies were suggested:

- “Kidney disease is comparable to cancer in terms of seriousness and mortality.”
- Patient empowerment
- Make it easy for clinicians

Other strategies included:

- Let the public know about the epidemic of kidney disease.

- Work along a continuum to emphasize risk: serious, common, preventable, and manageable.
- “Know your numbers.”
- It is less costly to pay for tests and screening than for later therapy.
- Clinical indicators and performance measures are important.
- Systems approach: electronic medical record popup messages and flowsheets for PCPs
- Family learning centers can be valuable in the physician’s office; a variety of materials are available for individuals of different ages.
- Focus and target the message for each audience: by disease category, impairment, or disability.
- Keep the message consistent.
- Try to reach people who do not see doctors.
- Deliver messages via many routes.
- Tailor messages to the audience.
- Develop strategies to allow health care professionals other than nephrologists to educate individuals at risk.
- Integrate messages with those of other public and professional education programs.
- Follow the lead of pharmaceutical companies in successful marketing to the public.
- Engage athletes; for example, Will Smith doing a rap video could be successful.
- Use celebrities pertinent to each audience.
- Encourage stories in *Parade* magazine and airline magazines.
- Use television talk shows and endorsements, for example, shows hosted by Rosie O’Donnell and Oprah Winfrey.
- Utilize the Web and validate the content of Web materials; NKDEP should give its “Good Housekeeping Seal of Approval” to appropriate, pertinent, and scientifically valid information.
- Find the NKDEP’s unique niche and do not repeat the messages of other similar organizations.
- Produce a “road map” for when patients are found at risk or with disease, tied to the stages of kidney disease being developed. This guideline on how to proceed should be addressed to the patient, the health care team, the family, the insurer – all the stakeholders and pertinent players – and should include medical, social, and education components as well as an integrated and consistent message.

Suggested program partners:

- Opinion leaders in high-risk communities
- Professional organizations including midlevel management
- Kidney organizations
- Health and life insurers
- The Leapfrog Group (a group that helps align health interests with employer interests)
- National and State public policymakers, and legislative aids and assistants
- State health departments
- The CDC
- Pharmacies
- Pharmacists
- Organization of human resource professionals
- Occupational health specialists
- School nurses
- Clergy

- Health professional training programs (including the AAMC) and licensing boards
- Subspecialty organizations
- plus other health, health-related, and health-interested organizations.

Regarding evaluation measures, it is important to build on existing measurement and evaluation efforts such as those used by the NCQA and Healthy People 2010. Other suggestions included:

- Public and individual awareness of the “kidney number”
- Percent of individuals having urinalysis (garnered from HEDIS guidelines and HMO databases)
- The percent of people reached by education messages in 2, 5, or 10 years
- Public awareness of risk factors for kidney disease, and prevalence and seriousness of the problems – after 2, 5, and 10 years
- Differences in NHANES data and BRFSS data (long-term measures)
- Changes in behavior of providers and lifestyle behavior of patients, such as decreased smoking, weight loss, and increased physical activity.

**Group 4 — Dr. Sharon Anderson, Oregon Health Sciences University, and
Dr. William McClellan, Georgia Medical Care Foundation**

Group 4 developed the following guidance outline for the NKDEP program.

The overarching goal of the NKDEP should be to decrease the incidence, prevalence, morbidity, mortality, and cost of CKD in the United States. Specific goals related to education include:

- Disseminate the message that CKD is a public health problem.
- Educate the population about kidney function and disease.
- Educate high-risk groups about their risk.
- Educate patients and providers about the “Gang of 4” (interrelated risk among kidney disease, diabetes, hypertension, and renal-retinal complications).
- Promote awareness that anyone can get kidney disease.
- Provide clear and consistent messages.
- Achieve medical community consensus on markers requiring intervention.
- Encourage early detection; all patients should have their urine and creatinine checked.
- Use unexpected or nontraditional opportunities within the health care system.
- Define and identify barriers to intervention.
- Get organizational change to happen.
- Define the target audience.
- Provide identification and care across the continuum of kidney disease.

Objectives:

- Develop education messages appropriate for the audiences.
- Broadly disseminate those education messages.
- Promote public literacy about kidney disease and its terminology, in part by developing a tagline or slogan.
- Use tightly focused programmatic activities.

- Consider replicating the JNC process as a model to develop consensus within the renal community about what should be known and what should be done; utilize existing resources such as the evolving K/DOQI document, where appropriate.
- Develop a clear and consistent message.
- Ensure the relevance and accuracy of the message by using formative research.
- Publicize the public health burden of CKD.
- K.I.S.S. – “keep it simple,” for providers and the public.
- Develop an effective evaluation strategy based in epidemiology and clinical science.

Target audiences, ranked in order of priority:

- high-risk and minority groups – diabetics, hypertensives, African-Americans, American Indians, etc.
- patients with CKD – patients already identified as having an elevated creatinine or proteinuria
- primary care providers
- patients with diabetes
- payers
- family members
- people who are obese

Other suggested groups included major employers, patients with special needs (hearing impaired, blind, illiterate, etc.), the Veterans Administration, the Indian Health Service, the Federal Employees Health Benefits Program (FEHBP; the insurance that covers all Federal employees), and Congress.

Important messages to communicate to minority groups:

- Risk factors for CKD
- Minority heritage is a risk factor
- Burden of disease and the risk of early death
- “Treatment helps.”
- Patient should be active and take control
- Importance of early detection
- “Know your number; challenge your physician.”
- Resources: NDEP strategies, ADA, NKF, NHBPEP, etc.
- Strategies: KEEP, minority support groups, religious community

Culturally sensitive and field-tested messages are needed to make sure that messages are being transmitted in a way in which they will be understood and appreciated.

Messages for patients who already have CKD:

- Know and understand the diagnosis, prognosis, systemic effects, potential complications (anemia, bone disease, etc.); there are actions or treatments that can work; patients’ families may be at some additional risk for CKD; renal replacement treatment options; and the financial issues and ramifications of having CKD.
- Resources: industry, NKF, AAKP, PKD Foundation, groups for individual renal diseases
- Strategies: empowerment, “the activated patient” – a patient who is aware, will take charge, and will demand the help they need. (In the early blood pressure control days, analyses of community programs showed that the greatest success in changing

awareness, detection, treatment, and control levels occurred in communities where patients were targeted with education messages.)

Messages for PCPs:

- Impact of CKD
- Role of early detection
- Effective treatment of CKD across the continuum of the disease
- Recognition of the associations of the “Gang of 4”
- Define and be consistent about the triggers for nephrology referral
- Issues specific to modality selection that PCPs should know (for example, avoiding blood transfusions in patients who might eventually get a transplant)
- Availability of support services (NKF, AAKP)
- Resources: industry
- Strategies: evidence-based practice guidelines

Messages for payers:

- “Early detection and treatment are cost effective.”
- “Evidence-based guidelines for kidney disease do (or will) exist.”
- “Neglect of these problems can be very expensive (the economic argument).”
- Strategies: HEDIS, “penny wise, pound foolish,” “an ounce of prevention”

Partner possibilities (that had not yet been discussed by other groups):

- American Association of Health Plans
- American Nurses Association
- Several groups attentive to the health needs of minority populations such as the Association of Black Cardiologists and the National Medical Association
- Unions
- Ophthalmologists
- American Association of Physician Assistants
- Association of Community Health Centers

Evaluation:

- Epidemiologic trends – any flattening of the line of incidence of ESRD or if NHANES survey 10 or 20 years in the future shows fewer patients with high creatinine
- Increased awareness of CKD among target groups (can purchase questions on the BFRSS to track awareness)
- Process measures (data from CMS, HCQIP)
- Earlier referrals (data can be derived from the 2728 forms, which are being revised)
- Changes in modality selections – with earlier and increased awareness, more patients may select peritoneal dialysis or home hemodialysis.

Group 5 — Dr. Neil Powe, American Society of General Internal Medicine and Johns Hopkins University School of Medicine, and Dr. Charles Clark, Indiana University School of Medicine

Group 5 developed the following guidance outline for the NKDEP program.

The overall program goal should be to prevent or reduce morbidity and mortality of CKD.

Objectives:

- Increase awareness of those at risk for CKD
- Increase identification of those at risk
- Improve early intervention
- Delay onset of ESRD
- Prepare for transition to dialysis, for those unable to delay onset of ESRD

Primary target audiences should be patients at risk because of:

- Diabetes or hypertension
- Proteinuria
- Abnormal serum creatinine
- Family history
- Genetic disorders

Low income and minority groups should receive special targeting emphasis.

Secondary target audiences should be providers:

- Primary care providers
- Non-physician providers who come into contact with patients

Tertiary target audiences should be payers, policymakers, and employers.

For the primary audience (patients), some effort should be undertaken to address the science questions:

- Absent the known risk factors, is there a scientific basis for screening the population at large?
- Can we develop a questionnaire or other evidence-based tool to identify those needing screening?
- Is there an age at which one becomes a screening target?

Messages for people at risk:

- Messages should be clear, concise, and easy to remember.
- Everyone needs to do better at caring for kidney disease.
- High-risk individuals can do a lot to prevent or delay the onset of renal failure.
- At-risk people should know their “numbers” – what they should be and what they need to do to get to the targeted values.
- Missed work days could be reduced by improving care.

Providers are the secondary audience; program messages to this audience should be how to identify and manage those at risk and how to partner with patients in participatory decisionmaking.

Target audience processes:

- Use the target audience as partners to define the message and the means to deliver the message.
- Ask: what can we do to help you?

- Buy-in is critical to success.
- May have to refine the goals and objectives after focus groups of targeted audiences.

How to reach target audiences:

- Use program partners.
- Use all means of communications (celebrities, media connections, etc.).

Potential partners: The only partner not mentioned by other groups was “everyone not on the FBI’s watch list”!

Evaluation needs to be built in and responsive to the program’s goals; solid baseline data is needed. The NKDEP’s evaluation needs to be integrated with the diabetes and blood pressure education programs. Measures could include:

- Percent at risk who are aware of their risk status
- Percent at risk who are screened
- Percent at risk who are prepared for dialysis

Potential barriers:

- Worksite or other kinds of screening may identify people with CKD against whom employers or others may then discriminate. Labeling individuals at the earliest stages of impaired renal function may be problematic.
- We do not understand fully who will and who will not progress from CKD to ESRD.
- We do not have consensus guidelines.
- We lack a clear and concise message.
- Increased identification of at-risk people and their treatment may be perceived to increase costs; better information about that perception is critical.
- A large proportion of the at-risk population has limited or no access to care, particularly health insurance (a huge barrier that must be surmounted).

Group 6 — Dr. Nicole Lurie, University of Minnesota, and Dr. Hanna Abboud, University of Texas Health Science Center at San Antonio

Group 6 developed the following guidance outline for the NKDEP program.

Program goals and objectives:

- Education
- Prevention
- Early detection and treatment of CKD
- Patient activation
- Advocacy for the NKDEP and for more work and awareness in this field

Target audiences:

- Public (children and adults)
- Patients with CKD
- High-risk populations
 - Diabetics
 - Hypertensives
 - Racial and ethnic minorities

- Families of ESRD patients
- Health care community – PCPs, health plans and health systems, Medicare and Medicaid, others who take primary or principle care of people likely to have CKD, the full array of other kinds of health care professionals who come in contact with people with CKD or in target populations.

Program messages and strategies:

- “Kidney disease is real.”
- “Kidney disease is preventable.”
- “If you have kidney disease, you can do something about it.” (to help deal with the fear and hopelessness surrounding a diagnosis of kidney disease)
- Patients and providers have shared responsibility for managing CKD.
- A “Save Your Kidneys” campaign.

Potential program partners not mentioned in prior groups:

- Emergency room physicians
- Dialysis centers, particularly in reaching families of patients with kidney disease
- Pharmacies
- State health department roles in surveillance activities
- NIH/NIDDK (a major partner; much applied research will need to be conducted as this program moves forward)

Evaluation:

- Gear to the ultimate goal, which is to reduce ESRD rates.
- Develop needed measures and build upon other measurement systems that already exist.
- Determine what resources are available.
- Clarify the responsibilities for data collection and monitoring. These systems are only partially in place currently, and don’t currently produce the answers needed to evaluate this program. It is not clear who or what organizations ought to be responsible for this kind of data collection and monitoring; this must be resolved.

Discussion

Discussion following the breakout group presentations included the following points:

- Dr. Paul Kimmel suggested that other partners or audiences should include emergency room physicians and ambulatory care centers.
- Dr. Paul Eggers stated the need for evidence-based economics to develop data on the cost-effectiveness of screening.

Industry Roundtable

Dr. Hostetter stated that three companies have taken an interest in pre-ESRD education. As a working group for industry is developed, other companies may come forward. In some areas, the three presenting companies are competitors, so Dr. Hostetter thanked them for sharing the results of their education programs.

Baxter Healthcare (Frank Parilla, Renal Division)

Mr. Parilla provided a brief background of Baxter, including its focus on renal therapy and the fact that it was the first company to make a hemodialysis machine commercially available. His presentation covered understanding and defining the problem of kidney disease, defining approaches to solving the problem, Baxter's Kidney Patient Educator (KPE) Program and its results, other Baxter initiatives, and key lessons learned from Baxter's experience.

The problem was defined as identifying the need for people at risk or diagnosed with kidney disease to better understand their disease and be able to make informed decisions about their care and their treatment options.

Market research studies indicated that the immediate impact of a diagnosis of kidney disease on patients is fear, resignation, uncertainty, and shock. Because of this initial reaction, timing of CKD-related information is critical to patients' receptivity to and acceptance of that information. Individuals have varied preferences for how they prefer to receive information, and some patients like to receive information in smaller amounts. Conversations with primary care providers, pamphlets and other written material, interaction with other patients, the Internet, and videos all can be effective, although with different individuals.

Baxter's KPE Program offers patients education sessions with a Baxter kidney nurse educator who has 5 to 7 years of experience. These sessions are available in areas with high concentrations of people with CKD. Each patient is offered a total of 3 to 4 hours of group, one-on-one, and telephone support. Topics include causes of renal failure, signs and symptoms of renal failure, therapy options, and general support. Using the KPE Program, Baxter has reached 900 referring physicians and a total of 26,500 patients have received this kidney-related education. Results of the program indicate that 45 percent of program participants said they might select home dialysis and 33 percent actually made that selection, compared with 12 percent nationwide. This finding indicates that education can make a difference.

Baxter's www.kidneydirections.com program is an education resource for patients and their families and friends to help plan for better kidney health using personalized planners, physician quotes, a glossary of terms, and links to other resources. Online material is available in English, Spanish, and Japanese. Results from this initiative show 100,000 unique visitors to the site, 1 million visits, and 6,000 registrants to the health planner option, which automatically e-mails new relevant information.

The goal of Baxter's Stay in Touch program is to supplement educational information for pre-ESRD patients. Developed in partnership with the American Association of Kidney Patients (AAKP) and launched in February 2000, this program consists of a series of six customized educational mailings in English and Spanish. The material is available through physicians' offices, the Internet, television, and on video, and can also be delivered directly to the patient's home. This program has enrolled 18,000 individuals.

The goal of Baxter's public awareness campaign was to increase awareness of kidney disease and the understanding of treatment options. Featuring basketball player Sean Elliott, the campaign was developed with the AAKP and the NKF. Its message, "Learn all you can" if you are at risk or have been diagnosed, was broadcast on a national tour and through public service announcements. The message was aired 5,000 times in 60 of the 100 top U.S. markets, constituting approximately 300,000 viewer media impressions. Viewers were directed to contact their physicians or health programs for more information. An audio version was released for radio play.

As part of its awareness campaign, Baxter piloted a direct response TV commercial in six markets, focusing on people diagnosed with kidney disease. The commercial carried an education message and offered the opportunity to obtain materials using a toll-free number. Results were that 13,000 people called the 800 number; the key lesson learned was that 2,500 of these calls were from people who were diagnosed with CKD or ESRD, 700 of the callers were at risk for developing CKD, and the other callers "just like to call 800 numbers"!

Each of Baxter's programs can stand separately, but they are also integrated. Overall key lessons learned were:

- The timing of education may play an important role in its success.
- Individuals like to receive information through a variety of channels and formats.
- The type of treatment selected is largely influenced by the degree of patient education.
- It is not easy to find pre-ESRD patients in general and at-risk populations.
- The challenge is how best to reach target audiences and engage them in kidney education programs.

Ortho Biotech (Susan Kadri, Director of Consumer Marketing)

Ms. Kadri presented an overview of CKD patient demographics. Two-thirds of CKD diagnoses are patients with hypertension and/or diabetes. In general, patients do not know the connection between diabetes and hypertension and CKD, the benefits of treating CKD before it progresses, or the basic terminology related to CKD such as creatinine and hemoglobin. It is essential that these messages be distributed widely to patients and health care providers.

In addition to lack of awareness of CKD and its connection to comorbidities, symptoms, and side effects, barriers to reaching patients include reluctance to deal with CKD – they have seen what has happened to others and prefer to ignore their own situation. The absence of an ongoing healthcare relationship can make an already anxiety-producing discussion even less likely to occur. For individuals for whom literacy is an issue or who may have difficulty accessing health care, an effective education tool is to rely on pictures to get messages across.

Ideas for reaching patients include:

- Use broad-based media programs such as TV, print, radio, and the Internet. Because patients are looking for information in various places, messages must be placed in all these areas.
- Conduct targeted media outreach to ethnic groups.

- Partner with minority associations and advocacy groups. Working together is the most effective method for disseminating patient materials; each person and organization has access to different patients.

Ms. Kadri briefly described two education programs currently underway that are supported by education grants from Ortho Biotech: the NKF's Kidney Early Evaluation Program (KEEP) and the BE ACTIVE™ Program for Physicians. KEEP identifies individuals at increased risk for kidney disease and encourages them to take action. It provides free screening for patients and empowers them to take action by seeking further care from a physician and through education. Appropriate followup is provided.

The BE ACTIVE™ Program for physicians encourages a dialog among nephrologists and between nephrologists and PCPs about CKD management, how each can be active in it, and how to form partnerships with patients. The program's premise is that earlier identification will improve patient outcomes, particularly in patients with diabetes or hypertension. BE ACTIVE™ stands for:

B	Blood pressure
E	Epoetin \propto
A	Access
C	Cardiovascular
T	Team work
I	Iron management
V	Vitamin D
E	Eat well & Exercise

Direct patient education materials should be kept simple and should include relevant definitions. A study in *Prevention* magazine reported that 75 percent of patients do not get enough time with their doctors, and 68 to 75 percent do not understand the messages conveyed to them by their doctors. Ortho Biotech's patient education materials include three brochures – linking CKD with diabetes and with high blood pressure as well as a patient guide to understanding CKD – and videos on the symptoms and side effects of CKD. All materials are produced in English and Spanish.

Ms. Kadri made the following next-step suggestions:

- Communicate to PCPs the value of early diagnosis and management.
- Communicate to patients via risk-factor counseling and patient education materials. Let patients know that something can be done about CKD.
- Research the messages to patients and professionals to make sure everyone “gets it.”
- Do not develop materials and then bring those materials to patients; talk with patients first and then develop the materials. Ask patients what words make sense and which definitions are understandable, and then have them repeat it back to make sure they understand.
- Start with the basics – who is at risk, what are the risk factors, what is the disease, what are key terms the doctor or nurse will talk about, why early treatment is important, and what questions to ask the doctor.
- Single-minded messages are the most effective; it is not necessary to talk about all things at once.
- Repetition is important.

Amgen, Inc. (Jean Kammerer, Program Development Manager)

Ms. Kammerer echoed the other presenters' concerns about the magnitude of the kidney disease problem in the United States. Amgen's approach has included brochures and booklets, a videotape on self-injection for peritoneal dialysis patients, a Web site (amgenrenaladvances.com), an Epogen® package insert for patients, and a live (by phone) clinical specialist program. Most written materials are provided in English, Spanish, and Chinese. Additional programs include a video and brochures for the "People Like Us" program, a booklet called "Getting the Most Out of Life," "Justin's Journey" for pediatric patients, a workbook and kit for home dialysis patients called "Epogen® and You," and the Life Options Rehabilitation Program.

Amgen has partnered with the Ochsner Clinic's Healthy Start Program in New Orleans to provide an ESRD preparedness program. Staffed by an MD, an RN, a registered dietitian, and a social worker, the goals of this program are education, active participation in care, and informed decisionmaking. Results to date with the 67 enrolled patients are that, compared with similar controls, the ESRD Preparedness Program patients began dialysis with significantly higher serum albumin levels, 43 percent had a fistula placed prior to initiation of dialysis, and 36 percent were able to use the fistula to initiate dialysis.

The "Life Options Rehabilitation Program," an Amgen partnership with Medical Education Institute, conducted research on patient recall and patient knowledge. The research concluded that people could not recall CKD-related symptoms unless prompted; however, when they were prompted, they reported multiple symptoms that would lead a health professional to suspect the presence of CKD. Most people did not know that it is possible to slow the progression of kidney disease.

Patients who were already diagnosed with CKD wanted more information about kidney disease. Other findings of this research included:

- Only 33 percent could name a common test for kidney disease.
- 57 percent did not know what common tests measure.
- 70 percent did not know that the progression of kidney disease could be slowed.
- 60 percent had no idea why they take EPO (these are people who were injecting themselves with EPO several times per week or per month).
- Most people had no knowledge about their medications.
- 50 percent of patients had a first degree relative with kidney problems.
- Only one-third of patients with diabetes or hypertension knew they were at risk for kidney disease.

The two critical questions asked by patients are "How long will I live?" and "How well will I live?" Although patients may not ask these questions aloud, they will act on their estimations of the answers. Until the renal field can answer those two questions, people will be unlikely to hear anything else. Ms. Kammerer suggested that the renal field stop using the word "end" in "end-stage renal disease," because this concept is very scary to almost all patients and has a chilling effect on hope and the desire to live.

Health professionals can offer encouragement to patients with kidney disease by focusing on the hope that life will be good, assisting patients in learning about the disease, and inspiring them to adhere to treatment advice.

Ms. Kammerer concluded by stating that Amgen has experience providing education materials and programs to people on dialysis. The company is interested in partnerships to improve the lives of patients with kidney disease.

Questions and Comments for the Industry Roundtable

1. *How can we better address the issue of fear, which was mentioned by all three presenters?* The fear is of the unknown – when patients do not know what is happening to them and what they can do to prevent what is happening. Care providers should work to eliminate fear. There will be some people who do not want to go on dialysis. Education is powerful but sometimes people’s culture influences them to believe that “life is meant to be this way.” Some people have horror stories about dialysis. If dialysis is not desired, other options should be presented; for example, home dialysis and hospice. Discussion about CKD may be the first time people hear statistics about survival rates and this discussion is likely to be frightening, but patients need to hear it earlier and the message should be delivered with compassion and hope.

2. *Regarding the effectiveness of education programs, what techniques can be used to measure improvement and to measure effectiveness of programs?* Awareness is a key measure. A baseline test can be administered through a market research company, then quarterly or annual (depending on the length of the program) retests can show whether the program has “moved the needle” on awareness. In addition, focus groups and quantitative surveys can answer whether program participants took any action and if not, why not. Other suggestions included obtaining ongoing feedback about the process of the education programs, tracking patients’ modality and therapy selections, and assessing at various points in time to compare with the initial market research information.

Education is a means, not an end. Measurement must assess whether people actually change their behavior; education materials by themselves will not cause action, but those materials must teach people how to do the right thing. This is especially true with providers – research shows that continuing medical education makes essentially no difference in physician performance.

3. *Since each company must differentiate itself from its competitors, how can simple, harmonized messages be utilized effectively?* All messages should stick to the basics; doing so helps everyone’s message. By increasing awareness, any education materials build on what has come before and prepare for what will come in the future. Basics can be repeated in a variety of formats produced by a variety of organizations or companies and should include a description of the disease and what patients can do about it, alongside the message that patients should talk to their health care provider.

Next Steps

Dr. Hostetter reiterated NIDDK's receptiveness to information and suggestions from individuals and groups. He stated that the results of this meeting will be published as a proceeding and that copies will be provided to participants. A steering or coordinating committee will be formed and working groups will be constituted to begin to craft the messages. He requested that participants e-mail him with additional ideas; he was particularly interested in the point about the need to support laboratory changes and would like to develop a workgroup to come up with ideas for user-friendlier laboratory reports. Dr. Hostetter also asked participants to think about individual people at each partner group who might be interested in working on the NKDEP, because personal interest is generally most effective in obtaining long-term commitment to this kind of education program.

Dr. Hostetter reminded participants that the NKDEP is being undertaken so that people at risk do not become patients. Beyond the important technical issues, the message developed must be informed by the message of hope.

The meeting was adjourned at 11:30 am.